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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/417,251 10/13/99 CAHOON

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E. I. DU PONT DE NEMOURS & CO.
LEGAL - PATENTS
1007 MARKET STREET
WILMINGTON DE 19898

EXAMINER

ZARA, J

ART UNIT	PAPER NUMBER
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1635

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DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)
	09/417,251	CAHOON ET AL.
Examiner	Art Unit	
Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____ .
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-35 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 16-30 and 35 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) Interview Summary (PTO-413) Paper No(s). ____ .
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

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DETAILED ACTION

Claims 16-35 are pending in the instant application.

Election/Restriction

Applicant's election with traverse of Group I, claims 16-30 and 35, and election with traverse of SEQ ID No: 9, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that a protein and the polynucleotide encoding it are not independent and distinct. This is not found persuasive because searches required for each of these groups would not be coextensive and furthermore the extensive databases which must be searched for properly and rigorously searching each group are distinct and independent. (i.e. The protein which is encoded by a nucleotide sequence can be obtained by other means such as by purification or extraction from a cellular source.) Applicants have argued further that the restriction requirement of a single nucleotide or amino acid sequence is improper and that the Examiner has ignored published agency policy which permits a reasonable number of nucleic acid or amino acid sequences to be examined in a single application without restriction. Contrary to Applicants' assertions, the current policy of the PTO is that restriction of an application to a single nucleotide or amino acid sequence is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-30 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe elements which are essential to the function of the claimed invention, which elements include those nucleotide sequences which are essential for functional protein disulfide isomerase activity. The specification does not disclose the nucleotide sequences which are at least 85% identical to a polypeptide of SEQ ID NO: 10 and which encodes a functional protein disulfide isomerase. The specification does not describe the elements which are essential to the genera comprising a protein disulfide isomerase family whereby functional homologues comprising at least 85%, 90% or 95% identity have been identified. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising protein disulfide isomerase homologues. The disclosure does not clarify or define what common attributes are encompassed by the genus comprising protein disulfide isomerase homologues. The scope of the claims includes numerous structural variants, and the genera are highly variant because a significant number of structural and/or sequence

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differences between members of the claimed genus is permitted. Concise structural features or requisite sequences or motifs that could distinguish members of the genus from others are missing from the disclosure. No common structural attributes identify the members of the genus comprising the claimed protein disulfide isomerase family. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. The specification fails to teach or adequately describe a representative number of species in the claimed genera such that the common attributes or characteristics concisely identifying members of the proposed genus are exemplified and hence the description provided in the instant disclosure is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicants were not in possession of the claimed genus.

Claims 16-30 and 35 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

The state of the prior art and the predictability or unpredictability of the art.

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The amount of direction or guidance presented in the specification AND the presence or absence of working examples. Applicants have not provided guidance in the specification for the functional expression of any protein disulfide isomerase.

The specification teaches the alignment of purported polypeptide sequences derived from EST sequences obtained from clones from various cDNA libraries, which alignments are compared to the previously characterized protein disulfide isomerase from *Humicola insolens* or *Bos taurus*. The specification fails to teach the functional expression of any purported polypeptides whereby protein disulfide isomerase activity has been obtained and a family of functional homologues have been characterized. One skilled in the art would not accept on its face the examples given in the specification of sequence alignments of purported polypeptide sequences obtained from cloned nucleotide fragments as being correlative or representative of the functional expression of protein disulfide isomerase homologues and further whereby the sequence requirements for determining all functional homologues comprising at least 85% identity have been delineated in view of the lack of guidance in the specification and known unpredictability associated with the ability to predict protein function from purported amino acid sequences. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with the sequence variations tolerated whereby a family of protein disulfide isomerase homologues have been identified.

The breadth of the claims and the quantity of experimentation required. The breadth of the claims is very broad. The claims are drawn to any and/or all protein disulfide

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isomerase homologues comprising at least 85% homology with protein disulfide isomerase from *Humicola insolens* or *Bos taurus*. In order to practice the invention claimed, it would require undue trial and error and undue experimentation beyond which is taught in the specification to practice the invention drawn to the identification of all protein disulfide isomerase homologues comprising at least 85% homology with protein disulfide isomerase from *Humicola insolens* or *Bos taurus*. The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of the nucleotide sequences necessary for functional protein disulfide isomerase activity whereby the nucleotide sequences encoding all homologues comprising at least 85% identity with the previously characterized protein disulfide isomerase from *Humicola insolens* or *Bos taurus* have been disclosed and protein disulfide isomerase activity has been demonstrated. Since the specification fails to provide any particular guidance for the functional expression of all the members of the claimed genus, and since determination of these factors for a particular isoform or homologue within the claimed genus is highly unpredictable, it would require undue experimentation to practice the invention claimed.

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

June 19, 2001



ANDREW WANG
PRIMARY EXAMINER